RR-609
TXR-479

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

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MEMORANDUM

Date: October 23, 1980

Subject: EPA Registration Number: 2829-RRO
Cunilate 2174-NA BASE: Caswell#

From: Deloris F. Graham 11/4/80 DFG
FHB/TSS E 11/5/80

To: Henry Jacoby
Product Manager (21)

Applicant: Thiokol/Ventron Division
150 Andover Street
Danvers, MA 01923

Active Ingredient:
Copper 8-quinolinolate 22%
Inert Ingredients 78%

Background: Dermal Irritation and Eye Irritation studies were submitted. These studies were conducted by International Research and Development Corporation, Mattawan, Michigan. These data are under accession number 242995. Cite-All method of support is used.

Recommendation:

1) The Dermal Irritation and Eye Irritation studies are acceptable to support the conditional registration of this product. However for future submission please note:

   a. In the Acute Dermal Study, 4 sites (2 abraded and 2 intact) must be used.

2) FHB/TSS could not find, based on the "Cite-All" method of support, any substantially similar product bearing the signal word DANGER. Therefore Acute Oral, Dermal and Inhalation studies must be submitted to fulfill the acute toxicity data requirements.

3) FHB/TSS objects to the conditional registration of this product until previously requested studies are submitted.

1/4

el:

Labeling comments reserved until previously requested data are submitted.

iew:

Eye Irritation Study: International Research and Development Corporation.

ocedure: 9 New Zealand white rabbits received a 0.1 ml dose of the test terial in the conjunctival sac of the right eye of each rabbit. Three of e nine rabbits were washed 30 seconds after instillation. Observations were de at 24, 48, 72 and 96 hours and at day 7 and every third day for 34 days. dy weights were recorded initially, at weekly intervals and at study rmination.

sults: 5/6 animals with treated unwashed eyes had corneal opacity at 24 urs (1/6 = 17.5, 3/6 = 40, 1/6 = 50) and persisted in 4/6 animals through y 7. 6/6 had iris irritation (6/6 = 5) and persisted in 3/6 through day 7. 6 had conjunctival redness (6/6 =) swelling (1/6 = 3.5, 5/6 = 4) and scharges (6/6 = 3). Conjunctival irritation persisted through day 7.

3 animals with treated washed eyes had corneal opacity at 24 hours which rsisted in 1/3 through day 7. 2/3 had iris irritation (1/3 = 5, 1/3 = 10) ich persisted through day 7 in 1/3 animals. 3/3 had conjunctival redness /3 = 3), swelling (1/3 = 3.5, 2/3 = 4.0) and discharge (3/3 = 3). njunctival irritation persisted through day 7.

udy Classification: Core Guideline Data

xicity Category: I-DANGER

Dermal Irritation Study: International Research and Development rporation.

ocedure: 3M and 3F New Zealand white rabbits were administered a 0.5 ml se of the test material under occlusive wrap for 24 hours. The animals were vided into 2 groups, three rabbits were assigned to an intact group and ree rabbits were assigned to an abraded group. Observations were made at 24 d 72 hours after test article application. Body weights were recorded at udy initiation and study termination.

sults: At 24 hours 3/3 of the intact group (3/3 =) and 1/3 of abraded oup (1/3 = 1) had slight erythema. 3/3 of the intact group (3/3 = 1) and /3 of the abraded group (1/3 = 1, 1/3 = 2, 1/3 = 3) had very slight to derate edema.

t 72 hours 3/3 of the intact group (3/3 = 1) and 3/3 of the abraded group 2/3 = 1, 1/3 = 2) had very slight to well defined erythema. 3/3 of the ntact group (1/3 = 1, 2/3 = 2) had very slight to well defined edema.

2

No mortalities. Two animals exhibited soft stool on day 1. Test site was discolored dark green. Other symptoms included fissuring, slight eschar and exfoliation. Dermal Irritation Score was 3.4.

Study Classification: Core Minimum Data. 4 sites (2 abraded and 2 intact) must be used.

Toxicity Catergory: III - CAUTION

Copper 8-quinolinolate Reviews

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Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

_x_ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
